DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 24,2014

Abeon Medical Corporation
Allison Slaga
Engineer
8000 Katherine Boulevard
Brecksville, Ohio 44141

Re: K142467
Trade/Device Name: Intelair Nasal Airway Support System
Regulation Number: 21 CFR 868.1400
Regulation Name: Carbon Dioxide Gas Analyzer
Regulatory Class: Class II
Product Code: CCK
Dated: October 22, 2014
Received: October 27, 2014

Dear Ms. Slaga,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin Keith
Director
Division of Anesthesiology,
General Hospital, Respiratory, Infection
Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142467

Device Name
Intelair Nasal Airway Support System

Indications for Use *(Describe)*
The device is indicated for use in patients requiring supplemental oxygenation, patients requiring capnographic monitoring, and patients requiring non-definitive airway support. To be used in one or any combination of the preceding circumstances.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

SECTION 5 - 510(K) SUMMARY

I. SUBMITTER

Abeon Medical Corporation
8000 Katherine Blvd.
Brecksville, Ohio 44141

Phone: 440-262-6000
Fax: 440-262-6002

Contact Person: Allison Slaga
Date Prepared: August 27, 2014

II. DEVICE

Name of the device: IntelAir Nasal Airway Support System
Common Name: Carbon Dioxide Gas Analyzer Accessory
Classification Name: Carbon Dioxide Gas Analyzer (21 CFR 868.1400)
Regulatory Class: II
Product Code: CCK

III. PREDICATE DEVICE

IntelAir Nasal Airway Support System, K131506
This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The subject device is a non-sterile, single-use airway support system that is intended to support airway patency, aid in supplemental oxygen delivery and assist in respiratory gas sample collection for capnogrpahy. The device consists of an airway tube, accessory tubes, and in some versions a magnetic securement system.

Device Identification

Model Numbers

- NR2126XX-YY; Includes the magnetic securement system, where XX represents the length (in centimeters) of the airway tube and YY represents the quantity of pouched devices in the boxed product.
- NR2026XX-YY; Does not include the magnetic securement system; XX represents the length (in centimeters) of the airway tube and YY represents the quantity of pouched devices in the boxed product.

Components

Nasal Airway Support System with Securement: Part Numbers NR2126XX-YY

- Retrieval Probe – Part of the magnetic securement system; Used to retrieve the catheter assembly from the nasopharynx.
- Catheter Assembly – Part of the magnetic securement system; Used to wrap the nasal septum.
- Stylet Assembly – Part of the magnetic securement system; Provides column strength to the catheter assembly for insertion.
- Airway Tube – Used as a conduit to support the airway and house the accessory tubes and clip.
- Accessory Tubes – Used to aid in the delivery of oxygen and sampling of carbon dioxide; Consists of two laterally bonded tubes that connect to the anesthesia machine and terminate at the distal end of the airway tube.
- Clip – Used to prevent dislocation of the accessory tubes within the airway tube.
- Removal Pick – Used to open the clip for accessory tube adjustment or removal.

Nasal Airway Support System: Part Numbers NR2026XX-YY

- Airway Tube – Used as a conduit to support the airway and house the accessory tubes and clip.
- Accessory Tubes – Used to aid in the delivery of oxygen and sampling of carbon dioxide; Consists of two laterally bonded tubes that connect to the anesthesia machine and terminate at the distal end of the airway tube.
- Clip – Used to prevent dislocation of the accessory tubes within the airway tube.
- Removal Pick – Used to open the clip for accessory tube adjustment or removal.

Environment of Use

The environment of use and target population of the subject device is substantially equivalent to the predicate device.

The subject device is for prescription use only and is limited to a duration of use no greater than 24 hours. The target population for the device is patients who are breathing spontaneously who require airway support, supplemental oxygen delivery, and capnographic monitoring. The device may be used for one or in any combination of the preceding circumstances. Clinical settings where the device may be useful include, but are not limited to, surgery centers, ambulatory units and endoscopy units.

Principle of Operation

The principle of operation for the subject device is substantially equivalent to the predicate device.

The subject device is a non-sterile, single use device. The accessory tubes consist of an oxygen delivery tube and a carbon dioxide sampling tube which are fitted with their respective connectors

at the proximal ends. The connectors may be attached to an anesthesia machine and are substantially equivalent to the predicate device. The distal ends of the accessory tubes are housed within the airway tube and terminate at the distal end of the airway tube.

The airway tube is designed to be inserted into the patient's nasal passage and terminate in the pharynx. Located at the proximal end of the airway tube is the clip which is used to prevent dislocation of the accessory tubes. The airway tube provides non-definitive airway support so that oxygen delivery and carbon dioxide gas sampling occurs within the pharynx.

Some versions of the device include magnetic securement components. The magnetically-tipped catheter assembly and retrieval probe may be inserted into each of the patient's nasal passages, connecting in the nasopharynx. Upon retrieval of the catheter assembly, the attached strand is wrapped around the nasal septum. The strand is used to secure the airway tube and accessory tubes to the patient and to prevent inadvertent displacement or unwanted removal of the device.

Materials of Use

The materials of the subject device are identical to the predicate device are substantially equivalent.

Patient-Contacting Materials – The following components are considered patient-contacting. All patient-contacting materials have been tested for biocompatibility according to the FDA Guidance and ISO-10993, or have been approved in a 510(k).

- Retrieval Probe (Duration: ≤ 24 hours; Contact: Mucosal Tissue)
    - Probe – Thermoplastic polymer
    - Magnet – Gold-plated magnet
- Catheter Assembly (Duration: ≤ 24 hours; Contact: Mucosal Tissue)
    - Catheter – Block copolymer
    - Strand – Woven polyester
    - Magnet – Gold-plated magnet
- Airway Tube – Silicone (Duration: ≤ 24 hours; Contact: Mucosal Tissue)
- Accessory Tubes (Duration: ≤ 24 hours; Contact: Externally Communicating with respiratory gas pathway)
    - Tubes – Polyvinyl chloride
    - Connectors – Polyvinyl chloride

Non Patient-Contacting Materials – The following components are not patient-contacting.

- Stylet Assembly
    - Stylet Handle – Thermoplastic polymer
    - Stylet Wire – Polymer-coated wire
- Clip – Thermoplastic polymer
- Removal Pick – Thermoplastic polymer
- Accessory Tube Flag – Adhesive paper
- Accessory Tube Tie – Polyamide

V. INDICATIONS FOR USE

The Indications for Use statement is identical to the predicate device:

The device is indicated for use in patients requiring supplemental oxygenation, patients requiring capnographic monitoring, and patients requiring non-definitive airway support. To be used in one or any combination of the preceding circumstances.

The contraindications are identical to the predicate device:

Contraindications include obstructions or abnormalities of the nasal passages, bleeding of the nasal passages or nasopharynx, facial, cranial, or basilar skull fractures, or other mid-face trauma. The devices are contraindicated for patient in respiratory arrest and patient taking anticoagulants or blood thinners. The devices should not be used on patients who may pull on the device to such a degree as to cause serious injury or harm.

The Intended Use statement is identical to the predicate device:

The device is intended to support airway patency, aid in supplemental oxygen delivery and assist in respiratory gas sample collection for capnography. This device is intended to be used for one or in any combination of the preceding procedures.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject and the predicate device share the technological principles of non-definitive airway support and delivery of supplemental oxygen and sampling of carbon dioxide within the pharynx. Once connected to the anesthesia machine, the device is inserted into the patient's nasal passage and terminates in the pharynx. At a high level, the subject and predicate device are based on the following same technological elements:

- Device is non-sterile and is for single-use.
- Device is inserted into the patient's nose and terminates in the pharynx.
- Device provides non-definitive airway support for patients who are breathing spontaneously.
- Device aids in the delivery of supplemental oxygen by connecting to an anesthesia machine and terminates in the pharynx.
- Device aids in respiratory gas sampling for capnography by connecting to an anesthesia machine and terminates in the pharynx.
- Device is in bodily contact with the mucosal tissue and the respiratory gas pathway.

The following technological differences exist between the subject device and the predicate device:

- The subject device is available in a version which does not include the magnetic securement components (retrieval probe assembly, catheter assembly and stylet assembly).

- The subject device may be secured to the patient using surgical tape (not included with the device).

VII. PEFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

The subject device and the predicate device are both considered mucosal tissue-contacting and externally communicating with the respiratory gas pathway for a duration less than 24 hours. The biocompatibility evaluation for patient-contacting components of the finished device was performed in accordance with the draft guidance entitled "Use of International Standard ISO-10993", 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'". The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Gentoxicity
- Pyrogenicity
- Subacute Toxicity
- Implantation

Mechanical Testing

The testing methods and functional specifications of the subject device are the same as the methods and specifications of the predicate device. The following mechanical tests were performed for the subject and predicate devices:

- Tensile Testing
- Compression Testing
- Flow Testing
- Leak Testing

VIII. CONCLUSIONS

By comparison, the subject device has been determined to be substantially equivalent to the predicate device through design validation. The components are similar in design, materials and operation. Design validations were conducted in accordance with the test methods and design specifications defined in by the predicate device to demonstrate safety and effectiveness. The predicate device and subject device have the same indications for use and intended use. The overall purpose and physiological impact of the predicate and subject devices remain the same. Contraindications for the predicate and subject devices are also identical.